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Ī Practitioner's Docket No.

P1067

PATENT

4-3

Preliminary Classification:

Proposed Class:

Subclass:

NOTE: "All applicants are requested to include a preliminary classification on newly filed patent applications. The preliminary classification, preferably class and subclass designations, should be identified in the upper right-hand comer of the letter of transmittal accompanying the application papers, for example 'Proposed Class 2, subclass 129.' " M.P.E.P. § 601, 7th ed.

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Box Patent Application** Assistant Commissioner for Patents Washington, D.C. 20231

### NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of

Inventor(s):

ALLEN, David M.

WARNING: 37 C.F.R. § 1.41(a)(1) points out:

"(a) A patent is applied for in the name or names of the actual inventor or inventors.

"(1) The inventorship of a nonprovisional application is that inventorship set forth in the oath or declaration as prescribed by § 1.63, except as provided for in § 1.53(d)(4) and § 1.63(d). If un cath or declaration as prescribed by § 1.63 is not filed during the pendency of a nonprovisional application, the inventorship is that inventorship set forth in the application papers filed pursuant to § 1.53(b), unless a petition under this paragraph accompanied by the fee set forth in § 1.17(i) is filed supplying or changing the name or names of the inventor or inventors.

For (title):

PENETRATING ANTIBIOTIC GEL FOR SOFT TISSUE DISEASES

### CERTIFICATION UNDER 37 C.F.R. § 1.10\* (Express Mail label number is mandatory.)

(Express Mail certification is optional.)

I hereby certify that this New Application Transmittal and the documents referred to as attached therein are being detailed with the United States Postal Service on this data 28 June 2001 in an envelope as "Express Mail Post Office to Addressee," mailing Label Number \_ in an envelope dressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

## / EL800128278l

PEREZ

(type or prifft) name of person mailing paper)

Signature of person/mailing pape

WARNING: Certificate of mailing (first class) or facsimile transmission procedures of 31-e.F.R. § 1.8 cannot be used to obtain a dute f mailing or transmission for this correspondence.

\*WARNING: Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. § 1.10(b).

"Since the filing I correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

(New Application Transmittal [4-1]—page 1 of 11)

| 1. Type of Application   |
|--|
| This new application is for a(n)   |
| (check one applicable item below)  |
| X□X Original (nonprovisional)  |
| ☐ Design   |
| ☐ Plant  |
| WARNING: Do not use this transmittal for a completion in the U.S. of an International Application under 3: U.S.C. § 371(c)(4), unless the International Application is being filed as a divisional, continuation or continuation-in-part application.  |
| WARNING: Do not use this transmittal for the filing of a provisional application.  |
| NOTE: If one of the following 3 items apply, then complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF A PRIOR U.S. APPLICATION CLAIMED and a NOTIFICATION IN PARENT APPLICATION OF THE FILING OF THIS CONTINUATION APPLICATION.   |
| ☐ Divisional.  |
| ☐ Continuation.  |
| ☐ Continuation-in-part (C-I-P).  |
| 2. Benefit of Prior U.S. Application(s) (35 U.S.C. §§ 119(e), 120, or 121)   |
| NOTE: A nonprovisional application may claim an invention disclosed in one or more prior filed copending nonprovisional applications or copending international applications designating the United States of America. In order for a nonprovisional application to claim the benefit of a prior filed copending nonprovisional application or copending international application of copending international application. |

- - Arnerica, each prior application must name as an inventor at least one inventor named in the later filed nonprovisional application and disclose the named inventor's invention claimed in at least one claim of the later filed nonprovisional application in the manner provided by the first paragraph of 35 U.S.C. § 112. Each prior application must also be:
    - (i) An international application entitled to a filing date in accordance with PCT Article 11 and designating the United States of America; or
      - (ii) Complete as set forth in § 1.51(b); or
    - (iii) Entitled to a filing date as set forth in § 1.53(b) or § 1.53(d) and include the basic filing fee set forth in § 1.16; or
    - (iv) Entitled to a filing date as set forth in § 1.53(b) and have paid therein the processing and retention fee set forth in § 1.21(I) within the time period set forth in § 1.53(f).

37 C.F.R. § 1.78(a)(1).

NOTE: If the new application being transmitted is a divisional, continuation or a continuation-in-part of a parent case, or where the parent case is an International Application which designated the U.S., or benefit of a prior provisional application is claimed, then check the following item and complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICA-TION(S) CLAIMED.

WARNING: If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. §§ 120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. §§ 120, 121 or 365(c). (35 U.S.C. § 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. §§ 119, 365(a) or 365(b).) For a c-i-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.

(New Application Transmittal [4-1]—page 2 of 11)

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☐ Citations

| (Rel.H2A- | 12/44          |  |
|-----------|----------------|--|
|           |                | 7-OKM 4-1 4.5  |
|           |                | •  |
|           |                |  |
| WARN      | ING:           | When the last day of pendency of a provisional application falls on a Saturday, Sunday, or Federal holiday within the District of Columbia, any nonprovisional application claiming benefit of the provisional application must be filed prior to the Saturday, Sunday, or Federal holiday within the District of Columbia. See 37 C.F.R. § 1.78(a)(3).  |
|           | •              | he new application being transmitted claims the benefit of prior U.S. application(s). Enclosed are ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.   |
| 3. Pap    | ers            | Enclosed   |
| A. R      | lequi<br>Desig | red for filing date under 37 C.F.R. § 1.53(b) (Regular) or 37 C.F.R. § 1.153 (n) Application   |
| 13        | Pag            | es of specification  |
| 4         | Pag            | es of claims   |
|           | She            | ets of drawing   |
| WARNII    | 1              | DO NOT submit original drawings. A high quality copy of the drawings should be supplied when filing a patent application. The drawings that are submitted to the Office must be on strong, white, smooth, and non-shiny paper and meet the standards according to § 1.84. If corrections to the drawings are necessary, they should be made to the original drawing and a high-quality copy of the corrected original drawing then submitted to the Office. Only one copy is required or desired. For comments on proposed then-new 37 C.F.R. § 1.84, see Notice of March 9, 1988 (1990 O.G. 57-62). |
| !         | the O          | tifying indicia, if provided, should include the application number or the title of the invention, for's name, docket number (if any), and the name and telephone number of a person to call if the first subject of the drawings to the proper application. This information should be placed a back of each sheet of drawing a minimum distance of 1.5 cm. (5/8 inch) down from the top page* 37 C.F.R. § 1.84(c)).  |
|           |                | (complete the following, if applicable)  |
|           | •              | e enclosed drawing(s) are photograph(s), and there is also attached a ETITION TO ACCEPT PHOTOGRAPH(S) AS DRAWING(S)." 37 C.F.R. 1.84(b).   |
|           | for            | mal  |
|           |                | ormal '  |
|           |                | Papers Enclosed  |
| P         | ages           | s of declaration and power of attorney   |
|           |                | s of abstract  |
|           | )ther          |  |
| _         |                | papers enclosed  |
| . Ц       | _              | endment to claims  |
|           | Ц              | Cancel in this applications claims before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)  |
|           |                | Add the claims shown on the attached amendment. (Claims added have been numbered consecutively following the highest numbered original claims.)  |
|           | Prel           | iminary Amendment  |
|           | Info           | rmation Disclosure Statement (37 C.F.R. § 1.98)  |
|           |                | m PTO-1449 (PTO/SB/08A and 08B)  |

5.

| (     |                                       | Declaration of Biological Deposit   |
|-------|---------------------------------------|---|
| ſ     |                                       | Submission of "Sequence Listing," computer readable copy and/or amendment<br>pertaining thereto for biotechnology invention containing nucleotide and/or<br>amino acid sequence.  |
| (     |                                       | Authorization of Attomey(s) to Accept and Follow Instructions from Representative   |
|       | ]                                     | Special Comments  |
|       |                                       | Other   |
| . Dec | clar                                  | ation or oath (including power of attorney)   |
| NOTE: | the<br>by<br>the<br>by<br>bei<br>dec  | ewly executed declaration is not required in a continuation or divisional application provided that prior nonprovisional application contained a declaration as required, the application being filled is all or lewer than all the inventors named in the prior application, there is no new matter in the dication being filled, and a copy of the executed declaration filled in the prior application (showing signature or an indication thereon that it was signed) is submitted. The copy must be accompanied a statement requesting deletion of the names of person(s) who are not inventors of the application of filled. If the declaration in the prior application was filled under § 1.47, then a copy of that laration must be filed accompanied by a copy of the decision granting § 1.47 status or, if a nonsigning son under § 1.47 has subsequently joined in a prior application, then a copy of the subsequently cuted declaration must be filled. See 37 C.F.R. §§ 1.63(d)(1)–(3). |
| NOTE: | abt<br>cou                            | eclaration filed to complete an application must be executed, identify the specification to which it rected, identify each inventor by full name including family name and at least one given name, without reviation together with any other given name or initial, and the residence, post office address and ntry or citizenship of each inventor, and state whether the inventor is a sole or joint inventor. 37 R. § 1.63(a)(1)–(4).   |
| NOTE: | as p<br>as p<br>is th<br>this<br>or p | inventorship of a nonprovisional application is that inventorship set forth in the oath or declaration rescribed by § 1.62, except as provided for in § 1.53(d)(4) and § 1.63(d). If an oath or declaration rescribed by § 1.63 is not filed during the pendency of a nonprovisional application, the inventorship at inventorship set forth in the application papers filed pursuant to § 1.53(b), unless a petition under paragraph accompanied by the fee set forth in § 1.17(i) is filed supplying or changing the name ames of the inventor or inventors." 37 C.F.R. § 1.41(a)(1).   |
| Ķ     |                                       | nclosed   |
|       | ı                                     | xecuted by  |
|       |                                       | (check all applicable boxes)  |
|       | [                                     | inventor(s).  |
|       | (                                     | legal representative of inventor(s). 37 C.F.R. §§ 1.42 or 1.43.   |
|       |                                       | joint inventor or person showing a proprietary interest on behalf of inventor who refused to sign or cannot be reached.   |
|       |                                       | This is the petition required by 37 C.F.R. § 1.47 and the statement required by 37 C.F.R. § 1.47 is also attached. See item 13 below for fee.   |
|       | ١                                     | ot Enclosed.  |
| • .   | may                                   | the filing is a completion in the U.S. of an International Application or where the completion of<br>I.S. application contains subject matter in addition to the International Application, the application<br>be treated as a continuation or continuation-in-part, as the case may be, utilizing ADDED PAGE<br>NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION CLAIMED.   |
| •     | D                                     | •   |
|       |                                       | (New Application Transmittal [4-1]—page 4 of 11)  |

(Rel 82A-12/99 Pub 605)

| (The d    | eclaration or oath, along with the surcharge required by 37 C.F.R. § 1.16(e) can be filed subsequently).  |
|-----------|---|
|           | ☐ Showing that the filing is authorized.  (not required unless called into question. 37 C.F.R. § 1.41(d))   |
| 6. Inven  | torship Statement   |
| WARNING   | If the named inventors are each not the inventors of all the claims an explanation, including the<br>ownership of the various claims at the time the last claimed invention was made, should be<br>submitted.   |
| The inve  | entorship for all the claims in this application are:   |
| ₽         | The same.   |
|           | or  |
|           | Not the same. An explanation, including the ownership of the various claims a the time the last claimed invention was made,   |
| •         | is submitted.   |
|           | □ will be submitted.  |
| 7. Langu  | age .   |
| Al<br>re  | n application including a signed oath or declaration may be filed in a language other than English.<br>In English translation of the non-English language application and the processing fee of \$130.00<br>Quired by 37 C.F.A. § 1.17(k) is required to be filed with the application, or within such time as may<br>a set by the Office. 37 C.F.A. § 1.52(d). |
|           | English   |
| ) <u></u> | Non-English   |
|           | ☐ The attached translation includes a statement that the translation is accurate. 37 C.F.R. § 1.52(d).  |
| 8. Assign | nment   |
| . 🗆       | An assignment of the invention to   |
|           |   |
|           | ☐ is attached. A separate ☐ "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or ☐ FORM PTO 1595 is also attached.  |
| •         | □ will follow:  |
| NOTE: "If | an assignment is submitted with a new application, send two separate letters-one for the application done for the assignment.* Notice of May 4, 1990 (1114 O.C. 77-78)  |

WARNING: A newly executed "CERTIFICATE UNDER 37 C.F.R. § 3.73(b)" must be filed when a continuation-in-part application is filed by an assignee. Notice of April 30, 1993, 1150 O.G. 62-64.

(New Application Transmittal [4-1]-page 5 of 11)

FORM 4-1

| 9. | Certified | С | рy |  |
|----|-----------|---|----|--|
|----|-----------|---|----|--|

Certified copy(ies) of application(s)

| Country   | A   | Appin. No.                    |                                     | Filed  |
|---|---|-------------------------------|-------------------------------------|--|
| Country   | A   | Appin. No.                    |                                     | Filed  |
| Country   | Α   | opln. No.                     | <del></del>                         | Filed  |
| from which priority is claime                             | ed  |                               | •                                   |  |
| ☐ is (are) attached.                                      |   |                               |                                     |  |
| ☐ will follow.  |   |                               |                                     |  |
| NOTE: The foreign application of declaration. 37 C.F.R. § | oming the basis .<br>1.55(a) and 1.63.      | for the clain                 | n for priority i                    | must be referred to in the oath  |
| g 120 is itself entitled to                               | auonal Application<br>priority from a prio  | n from which<br>or foreion ao | ) this applicati<br>Olication, thei | filed directly relates. If any partition claims benefit under 35 U.S<br>in complete item 18 on the ADE<br>TOF PRIOR U.S. APPLICATION |
| 10. Fee Calculation (37 C                                 | .F.R. § 1.16)                               |                               |                                     |  |
| A. Regular application                                    | on  |                               |                                     |  |
|   | CLAIMS                                      | S AS FILE                     |                                     |  |
| Number filed  | Numbe                                       | er Extra                      | Rate                                | Basic Fee<br>37 C.F.R. § 1.16(a<br>\$710.00  |
| Total<br>Claims (37 C.F.R.<br>§ 1.16(c))                  | · 20 =                                      | 7                             | × \$ 18.0                           | 00   |
| ndependent  |   | 3                             | ν φ 10.0                            | \$54.00  |
| Claims (37 C.F.R.   |   |                               |                                     |  |
| 3 1.16(b))  | 3 =   | >                             | <b>\$80.</b> 0                      | 00   |
| Multiple dependent claim(s), if any (37 C.F.R. § 1.16(d)) |   | +                             | \$270                               | .00  |
| ☐ Amendment cance ☐ Amendment delet ☐ Fee for extra clair | ing multiple-de                             | pendenci                      | es is enclo                         | osed.  |
| NOTE: If the fees for extra claims                        | are not paid on filin<br>the time period se | ng they must<br>at for respon | be paid or the                      | e claims cancelled by amendme<br>itent and Tradernark Office in a  |
|   | Filing Fee Cal                              |                               |                                     | <b>s</b> 764.00  |
| B.   Design application                                   | <u>-</u>                                    |                               |                                     |  |
| (\$320,0037 C.F.  | R. § 1.16(f))                               |                               |                                     | •  |

| Hel #2A-12  | MY Pub.nUS)  | FORM 4-I   | 4-4   |                            |
|-------------|--|--|---|----------------------------|
|             |  | ·  |   |                            |
| <b>c.</b> 🗆 | Plant application (\$490.0037 C.F.F  | R. 6 1.16(a))  | ·   |                            |
|             |  | Filing fee calculation   | <b>\$</b>   |                            |
| 11. Sma     | all Entity Statement   | -  |   |                            |
|             | Statement(s) that this (are) attached.   | ils is a filing by a small entity under  | 37 C.F.R. § 1.9 and 1.27  |                            |
|             | the status is available affect any other application indirectly dependent usefuling of an application a continued prosecution a new determination as application. A nonpress 365(c) of a prior application or in the preference to the state statement in the prior desired. The payment of for purposes of this set | and desired. Status as a small entity in one cation or patent, including applications o pon the application or patent in which the sn under § 1.53 as a continuation, division, on application under § 1.53(d)), or the filing is to continued entitlement to small entity statistically application claiming benefit under 3 cation, or a reissue application may rely o attent if the nonprovisional application or the ment in the prior application or in the papplication or in the papplication or in the patent and status as a filthe small entity basic statutory filing toe winction." 37 C.F.R. § 1.28(a)(2). | a application or patent does not<br>if patents which are directly or<br>tatus has been established. The<br>ir continuation-in-part (including<br>of a raissue application requires<br>tus for the continuing or reissue<br>5 U.S.C. § 119(e), 120, 121, or<br>in a statement tiled in the prior<br>a reissue application includes a<br>tent or includes a copy of the<br>in small entity is still proper and<br>the treated as such a reference |                            |
| WARNING     | can unequivocally ma<br>1996 (emphasis added   |  | sons signing the statement<br>§ 509.03, Gin ud., rev. 2, July   |                            |
| _           |  | plete the following, if applicable)  |   |                            |
|             |  | ntity was claimed in prior applicat  |   |                            |
|             | is being claimed for   | this application under:  | , from which benefit  |                            |
|             | 35 U.S.C. § 🗍 1  | 19(e),<br>20,<br>21,<br>65(c),   |   |                            |
|             |  | us a small entity is still proper and  |   |                            |
|             | _ '  | •  | •   |                            |
|             |  | statement in the prior application   |   | +:+1ad +a                  |
| <i>:</i>    | · mig i se Calcu   | lation (50% of A, B or C above)<br>\$ 382.00   | Applicant is enclaims small enfor purposes of   | tity status                |
| · ar        | ny excess of the full fee pai<br>is filed within 2 months of<br>tendable under § 1,136, 3  | d will be refunded if small entitly status is es<br>I the date of timely payment of a full fee.<br>17 C.F.R. § 1.28(a).  | tablished and a refund assured  | reduced feet<br>under SEC. |
| 2. Requ     | est for Internationa   | I-Type Search (37 C.F.R. § 1.104   | (d))  | 41(a) & 41(t<br>U.S.C.     |
|             |  | (complete, if applicable)  |   |                            |
|             | Please prepare an int<br>when national exami   | ernational-type search report for th<br>nation on the merits takes place.  | is application at the time  |                            |

| 13. Fe Pay                  | ment Being Made at This Time   |                |              |       |
|-----------------------------|--|----------------|--------------|-------|
|                             | t Enclosed   |                |              |       |
|                             | No filing fee is to be paid at this time. (This and the surcharge required by 37 C.F.R. subsequently.)   | § 1.16(e)      | can be       | paic  |
| ☑ End                       | closed   |                |              |       |
| 图                           | Filing fee   | \$             | 382.00       | כ     |
|                             | Recording assignment (\$40.00; 37 C.F.R. § 1.21(h)) (See attached "COVER SHEET FOR ASSIGNMENT ACCOMPANYING NEW APPLICATION".)  | \$             |              | -     |
|                             | Petition fee for filing by other than all the inventors or person on behalf of the inventor where inventor refused to sign or cannot be reached (\$130.00; 37 C.F.R. §§ 1.47 and 1.17(i))  | \$             |              |       |
|                             | For processing an application with a specification in a non-English language (\$130.00; 37 C.F.R. §§ 1.52(d) and 1.17(k))  | æ.             |              |       |
| . 0                         | Processing and retention fee (\$130.00; 37 C.F.R. §§ 1.53(d) and 1.21(l))  | Ψ.<br>•        |              |       |
|                             | Fee for international-type search report (\$40.00; 37 C.F.R. § 1.21(e))  |                |              | ·     |
| 37 C.F.F.<br>either th      | <ol> <li>\$ 1.21(I) establishes a fee for processing and retaining any applit<br/>complete the application pursuant to 37 C.F.R. § 1.53(I) and this<br/>I. §§ 1.53 and 1.78(a)(I), indicate that in order to obtain the benefi-<br/>beneficial basic filing fee must be paid, or the processing and retention fee<br/>year from notification under § 53(I).</li> </ol> | s, as well as  | the change   | \$ 10 |
|                             | Total fees enclosed  | <b>s</b> _ 382 | 2.00         |       |
| 14. Method o                | f Payment of Fees  | V              |              |       |
|                             |  | 3802)          |              |       |
| \$                          | ge Account No.   | in the         | amount       | of    |
|                             | plicate of this transmittal is attached.   |                |              |       |
| NOTE: Fees sho<br>§ 1.22(b) | uld be itemized in such a manner that it is clear for which purpose  | the fees are   | paid. 37 C.I | F.A.  |

(New Application Transmittal [4-1]—page 8 of 11)

§ 1.136(a)(3).

| WARN  | ING: .                     | ization to Charge Additional Fees  If no fees are to be paid on filing, the following items should <u>not</u> be completed.  Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges, if extra claim charges are authorized.   |
|-------|----------------------------|--|
| C     | וד כ                       | ne Commissioner is hereby authorized to charge the following additional fees this paper and during the entire pendency of this application to Account No.  |
|       |                            | 37 C.F.R. § 1.16(a), (f) or (g) (filing fees)  |
|       |                            | 37 C.F.R. § 1.16(b), (c) and (d) (presentation of extra claims)  |
| NOTE: | must<br>set fo<br>to aut   | use additional fees for excess or multiple dependent claims not paid on filing or on later presentation only be paid or these claims cancelled by amendment prior to the expiration of the time period or response by the PTO in any notice of fee deficiency (37 C.F.R. § 1.16(d)), it might be best not thorize the PTO to charge additional claim fees, except possibly when dealing with amendments final action.  |
|       | Ö                          | 37 C.F.R. § 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)   |
|       |                            | 37 C.F.R. § 1.17(a)(1)-(5) (extension fees pursuant to § 1.136(a)).  |
|       |                            | 37 C.F.R. § 1.17 (application processing fees)   |
| NOTE: | as inc<br>charge<br>constr | A written request may be submitted in an application that is an authorization to treat any concurrent use reply, requiring a petition for an extension of time under this paragraph for its timely submission, or porating a petition for extension of time for the appropriate length of time. An authorization to be all required extension of time fees will be treated as a nuctive petition for an extension of time in any concurrent or future reply requiring a petition for entersion of time for an extension of time in any concurrent or future reply requiring a petition for entersion of time representation. |

☐ 37 C.F.R. § 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. § 1.311(b))

an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R.

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 C.F.R. § 1.311(b).

NOTE: 37 C.F.R. § 1.28(b) requires "Notification of any change in status resulting in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying, . . . the issue fee. . . " From the wording of 37 C.F.R. § 1.28(b), (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

(New Application Transmittal [4-1]-page 9 of 11)

| 16. Instructions as to Overpayme | en | t |
|----------------------------------|----|---|
|----------------------------------|----|---|

NOTE: ". . . Amounts of twenty-fiv dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-live dollars may be returned by check or, if requested, by credit to a deposit account. 37 C.F.A. § 1.26(a).

ORANGE ACCOUNT NO.

Credit Account No.

Refund

Reg. No.

Tel. No. (360) 647-1976

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(New Application Transmittal [4-1]—page 10 of 11)

(Rcl.82A-12/99 Pub.605)

**FORM 4-1** 

4-12

| X | Incorporation | by reference   | of | added    | pages |
|---|---------------|----------------|----|----------|-------|
|   | (check the    | fallowing them | :4 | <b>.</b> |       |

(check the following item if the application in this transmittal claims the benefit of prior U.S. application(s) (including an international application entering the U.S. stage as a continuation, divisional or C-I-P application) and complete and attach the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED)

|  | ⊠  | Plus Added Pages for New Application Transmittal Where Benefit of Prior U.S Application(s) Claimed   |  |
|--|--|--|--|
|  |  | Number of pages added5   |  |
|  |  | Plus Added Pages for Papers Referred to in Item 4 Above  |  |
|  |  | Number of pages added  |  |
|  |  | Plus added pages deleting names of inventor(s) named in prior application(s) who is/are no longer inventor(s) of the subject matter claimed in this application. |  |
|  |  | Number of pages added  |  |
|  |  | Plus "Assignment Cover Letter Accompanying New Application"  |  |
|  |  | Number of pages added  |  |
|  | Statement Where No Further Pages Added   |  |  |
|  | (if no further pages form a part of this Transmittal, then end this Transmittal with this page and check the following item) |  |  |
|  |  | This transmittal and with this age.  |  |

transmittal ends with this page.

# ADDED PAGES FOR APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED

NOTE: See 37 CFR 1.78.

#### 17. Relate Back

WARNING: If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. 120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. 120, 121 or 365(c). (35 U.S.C. 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. 119, 365(a) or 365(b).) For a c-i-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.

(complete the following, if applicable)

Amend the specification by inserting, before the first line, the following sentence:

### A. 35 U.S.C. 119(e)

NOTE: "Any nonprovisional application claiming the benefit of one or more prior filed copending provisional applications must contain or be amended to contain in the first sentence of the specification following the title a reference to each such prior provisional application, identifying it as a provisional application, and including the provisional application number (consisting of series code and serial number)," 37 C.F.R. § 1.78(a)(4).

"This application claims the benefit of U.S. Provisional Application(s) No(s).:

| APPLICATION NO(S).: | FILING DATE |
|---------------------|-------------|
| 60 /214,809         | 06/28/00    |
| /                   |             |
| /                   |             |

(Added Pages for Application Transmittal Where Benefit of Prior U.S. Application(s) Claimed

[4-1.1]—page 1 of 5)

| B. 35   | U.S.C. 120, 121 and 365(c)  |   |  |  |
|---------|---|---|--|--|
| NOTE:   | "Except for a continued prosecuti n application filed under § 1 claiming the benefit of on or more prior filed copending n not applications designating the United States of America must confirst sentence of the specification following the title a reference to it by application number (consisting of the series code and series number and international filing date and indicating the relation references to other related applications may be made when ap § 1.78(a)(2).  | rovisi nal applications or internationa<br>tain or be amended to contain in the<br>each such prior application, identifying<br>al number) or international application<br>ship of the applications. Cross |  |  |
|         | This application is a   |   |  |  |
|         | ☐ continuation  |   |  |  |
|         | ☐ continuation-in-part  |   |  |  |
|         | ☐ divisional  |   |  |  |
| C       | of copending application(s)   |   |  |  |
|         |   | filed on"   |  |  |
|         |   |   |  |  |
|         | and which designate   |   |  |  |
| NOTE:   | The proper reference to a prior filed PCT application that entere serial number and the filing date of the PCT application that de  | d the U.S. national phase is the U.S signated the U.S.  |  |  |
| NOTE:   | (1) Where the application being transmitted adds subject matter<br>the filing can be as a continuation-in-part or (2) if it is desired to<br>can be as a continuation.  | to the International Application, ther<br>do so for other reasons then the filing   |  |  |
| NOTE:   | The deadline for entering the national phase in the U.S. for an in the Notice of April 28, 1987 (1079 O.G. 32 to 46) as follows:  | ntemational application was clarified   |  |  |
|         | "The Patent and Trademark Office considers the International application to be pending until the 22nd month from the priority date if the United States has been designated and no Demand for International Preliminary Examination has been filed prior to the expiration of the 19th month from the priority date and until the 32nd month from the priority date if a Demand for International Preliminary Examination which elected the United States of America has been filed prior to the expiration of the 19th month from the priority date, provided that a copy of the international application has been communicated to the Patent and Trademark Office within the 20 or 30 month period respectively. If a copy of the international application has not been communicated to the Patent and Trademark Office within the 20 or 30 month period respectively, the international application becomes abandoned as to the United States 20 or 30 months from the priority date respectively. These periods have been placed in the rules as paragraph (h) of § 1.494 and paragraph (i) of § 1.495. A continuing application under 35 U.S.C. 365(c) and 120 may be filed anytime during the pendency of the international application." |   |  |  |
|         | The nonprovisional application designated above   | e, namely application   |  |  |
|         | U.S. Provisional Application(s) No(s).:   | , claims the benefit of   |  |  |
| APPLICA | ATION NO(S).:   | FILING DATE   |  |  |
|         | 1   |   |  |  |
|         | /   |   |  |  |
|         | /   | 33  |  |  |
|         |   |   |  |  |
| ت       | Where more than one reference is made above, printo one sentence.   | DIEASE COMDINE AII references   |  |  |

## 18. Relate Ba k—35 U.S.C. 119 Pri rity Claim f r Prior Applicati n

The prior U.S. application(s), including any prior International Application designating the U.S., identified above in item 17B, in turn itself claim(s) foreign priority(i s) as follows:

|   | Country   | Appin. no.                       | Filed on                             |  |  |
|---|---|----------------------------------|--------------------------------------|--|--|
| The certified copy(ies) has (have)  |   |                                  |                                      |  |  |
|   | been filed on<br>filed on   | , in prior application 0         | /, which was                         |  |  |
|   | is (are) attached.  |                                  |                                      |  |  |
| WARNING: The certified copy of the priority application that may have been communicated to the PTO by the International Bureau may not be relied on without any need to file a certified copy of the priority application in the continuing application. This is so because the certified copy of the priority application communicated by the International Bureau is placed in a folder and is not assigned a U.S. serial number unless the national stage is entered. Such folders are disposed of if the national stage is not entered. Therefore, such certified copies may not be available if needed later in the prosecution of a continuing application. An alternative would be to physically remove the priority documents from the folders and transfer them to the continuing application. The resources required to request transfer, retrieve the folders, make suitable record notations, transfer the certified copies, enter and make a record of such copies in the Continuing Application are substantial. Accordingly, the priority documents in folders of international applications that have not entered the national stage may not be relied on. Notice of April 28, 1987 (1079 O.G. 32 to 46). |   |                                  |                                      |  |  |
| 19. Ma  | intenance of Copen  | dency of Prior Applicat          | ion                                  |  |  |
| NOTE:   | NOTE: The PTO finds it useful if a copy of the petition filed in the prior application extending the term for response is filed with the papers constituting the filing of the continuation application. Notice of November 5, 1985 (1060 0.G. 27). |                                  |                                      |  |  |
| A. 🗆  | A.   Extension of time in prior application   |                                  |                                      |  |  |
| (Th   | (This item <b>must</b> be completed and the papers filed <b>in the prior application</b> , if the period set in the prior application has run.)   |                                  |                                      |  |  |
|   | A petition, fee and res   | ponse extends the term in t      | the pending <b>prior</b> application |  |  |
|   | ☐ A copy of the pet   | ition filed in prior application | on is attached.                      |  |  |
| B. 🗆  | Conditional Petition for  | r Extension of Time in Prior     | Application                          |  |  |
|   | (complete this  | item, if previous item not a     | pplicable)                           |  |  |
|   | A conditional petition application.   | for extension of time is bei     | ng filed in the pending prior        |  |  |
|   | ☐ A copy of the con   | ditional petition filed in the   | prior application is attached.       |  |  |
|   |   |                                  |                                      |  |  |
|   |   |                                  |                                      |  |  |

(Added Pages for Application Transmittal Where Benefit of Prior U.S. Application(s) Claimed [4-1.1]—page 3 of 5)

| 20. |  | th i     | r Inv nt r hip Stat m nt Wher B n fit f Pri r Applicati n(s)<br>d   |
|-----|--|----------|---|
|     |  |          | (complete applicable item (a), (b) and/or (c) below)  |
|     |  |          | s application discloses and claims only subject matter disclosed in the prior<br>plication whose particulars are set out above and the inventor(s) in this<br>plication are |
|     |  |          | the same.   |
|     |  |          | less than those named in the prior application. It is requested that the following inventor(s) identified for the prior application be deleted:                             |
|     |  |          | (type name(s) of inventor(s) to be deleted)   |
| (b) | This application discloses and claims additional disclosure by amendment a new declaration or oath is being filed. With respect to the prior application inventor(s) in this application are |          |   |
|     |  |          | the same.   |
|     |  |          | the following additional inventor(s) have been added:   |
|     |  |          | (type name(s) of inventor(s) to be added)   |
| (c) | The inventorship for all the claims in this application are  |          |   |
|     |  | <b>X</b> | the same.   |
|     |  |          | not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made   |
|     |  |          | is submitted.   |
|     |  |          | □ will be submitted   |

| •  |
|--|
| 21. Aband nm nt f Pri r Appli ati n (if applicable)  |
| Please abandon the prior application at a time while the prior application pending, or when the petition for extension of time or to revive in that application is granted, and when this application is granted a filing date, so as to make the application copending with said prior application.   |
| NOTE: According to the Notice of May 13, 1983 (103, TMOG 6-7), the filing of a continuation or continuation part application is a proper response with respect to a petition for extension of time or a petition revive and should include the express abandonment of the prior application conditioned upon granting of the petition and the granting of a filing date to the continuing application.   |
| 22. Petition for Suspension of Prosecution for the Time Necessary to File an Amendment   |
| WARNING: "The claims of a new application may be finally rejected in the first Office action in those situation where (1) the new application is a continuing application of, or a substitute for, an earlier application and (2) all the claims of the new application (a) are drawn to the same invention claimed in earlier application, and (b) would have been properly finally rejected on the grounds of art of recein the next Office action if they had been entered in the earlier application." MPEP, § 706.076 6th ed., rev.2. |
| NOTE: Where it is possible that the claims on file will give rise to a first action final for this continuation applicate and for some reason an amendment cannot be filed promptly (e.g., experimental data is being gather it may be desirable to file a petition for suspension of prosecution for the time necessary.  |
| (check the next item, if applicable)   |
| There is provided herewith a Petition To Suspend Prosecution for the Tin<br>Necessary to File An Amendment (New Application Filed Concurrently)  |
| 23. Small Entity (37 CFR § 1.28(a))  |
| <ul> <li>Applicant has established small entity status by the filing of a statement in pare application / on</li> </ul>  |
| ☐ A copy of the statement previously filed is included.  WARNING: See 37 CFR § 1.28(a).  |
| 24. NOTIFICATION IN PARENT APPLICATION OF THIS FILING  |
| <ul> <li>A notification of the filing of this<br/>(check one of the following)</li> </ul>  |
| continuation   |
| ☐ continuation-in-part   |
| ☐ divisional   |
| is being filed in the parent application, from which this application claims priority under ; U.S.C. § 120.  |

(Added Pages for Application Transmittal Where Benefit of Prior U.S. Application(s) Claimed [4-1.1]—page 5 of 5)



| Practi     | tioner's D cket N . $\frac{P106}{}$   | 7  | PATENT                            |
|------------|---|--|-----------------------------------|
|            | IN THE UNITED STATES  | ,<br>PATENT AND TRADEM.  | ARK FFICE                         |
| In re ap   | pplication of: ALLEN, Da  | vid M.   |                                   |
| Being F    | iled Herewith.  |  |                                   |
| For:       | PENETRATING ANTIBI  | OTIC GEL FOR SOFT  | TISSUE DISEASE<br>•               |
|            | nt Commissioner for Patents gton, D.C. 20231  |  |                                   |
|            | UNDER<br>37 C   | JBLICATION OF APPL<br>35 U.S.C. § 122(b)<br>F.R. § 1.213(a)                                      | ICATION                           |
| NOTE:      | 37 C.F.R. 1.213 (a) states: "If the inve<br>the subject of an application filed in a<br>that requires publication of applications<br>under 35 U.S.C. 122(b) and § 1.211 p | nother country, or under a multila<br>eighteen months after filing, the ap                       | iteral international agreement,   |
|            | (1) A request (nonpublication reques  |  |                                   |
|            | (2) The request states in a conspicut<br>U.S.C. 122(b);   | ous manner that the application is   | not to be published under 35      |
|            | (3) The request contains a certificati<br>and will not be the subject of an appli-<br>agreement, that requires publication  | cation filed in another country, or ur   | nder a multilateral international |
|            | (4) The request is signed in complia  | nce with § 1.33(b)."   |                                   |
| 1. This    | request is being submitted wil  | h this application on filing.  |                                   |
| 2. It is   | requested that this application   | on not be published unde   | er 35 U.S.C. 122(b).              |
|            | (When using Express Mail, the   | ER 37 C.F.R. §§ 1.8(a) and 1<br>Express Mail label number is ma<br>I certification is optional.) | i.10°<br>andatory;                |
| I hereby o | certify that, on the date shown below, to   | his correspondence is being:   |                                   |
|            |   | MAILING  | #: ••                             |
| for Pa     | sited with the United States Postal Sentents, Washington, D.C. 20231 37 C.F.R. § 1:8(a) sufficient postage as first class mail.   | vice in an envelope addressed to  37 C.F.R.  as "Express Mail Post Off Mailing Label No          | § 1.10 °                          |

☐ facsimile transmitted to the Patent and Trademark Office (703)

Date: 28 June 2001

(Request for Nonpublication of Application) [25-1]—page 1 of 2)

(type or print name of person certifying)

3. This is to certify that the invention disclosed in this application has not been and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

NOTE: 37 C.F.R. 1.33(b): "(b) Amendments and ther papers. Amendments and other papers, except for written assertions pursuant t § 1.27(c)(2)(ii) f this part, filed in the application must be signed by:

- (1) A registered attorney or agent of record appointed in compliance with § 1.34(b);
- (2) A registered attorney or agent not of record who acts in a representative capacity under the provisions of § 1.34(a);
- (3) An assignee as provided for under § 3.71(b) of this chapter; or
- (4) All of the applicants (§ 1.41(b)) for patent, unless there is an assignee of the entire interest and such assignee has taken action in the application in accordance with § 3.71 of this chapter."

Signature

(Type name of person signing)

/\/\/\/\/\/\/\

GUATURE OF PRACTITIONER

TODD N. CHA/THAWAY

(type or print name of practitioner)

119 N. Commercia**/** St., #620

P.O. Address

Bellingham, WA 98225-4437

(Request for Nonpublication of Application) [25-1]-page 2 of 2)

(Rel 85--1170) Pub 605)

Reg. No.: 32,991

Customer No.:

**Tel. No.: (** 360 ) 647.-

08-1254

FORAL 25.1

20: 1